REMARKS

The election of claims 1-7, 11, 23-27, 34-37 without traverse is noted.

The specification has been checked and various spelling and typographical and grammatical errors have been corrected. Also, the Abstract of the Disclosure has been revised in accordance with MPEP §608.01(b) and is newly presented herewith on an attached separate sheet.

The objection to informal drawings is noted. It is requested that the requirement for formal drawings be held in abeyance pending allowance of this application.

Dependent claim 5 has been rejected under 35 USC §112, ¶1, as containing subject matter not described in the specification. This rejection is respectfully traversed.

Claim 5 as originally filed in this application constitutes a portion of the specification, and the subject matter of claim 5 is submitted to be directly connected to the subject matter of claim 1 from which it depends regarding a subxiphoid incision and "... one additional subxiphoid incision." It is therefore respectfully submitted that the subject matter of dependent claim 5 is adequately supported by the specification as filed, and that dependent claim 5 is patentable to applicant.

Claims 1-4, 6-7 and 25-27 have been rejected under 35 USC §102(b) as being anticipated by Oliva '156. This rejection is respectfully traversed.

These claims, which have been amended merely to define the invention more specifically, now specifically recite variously "inserting a rigid endoscopic cannula having a transparent tip at a distal end thereof; (c) advancing the tip of said endoscopic cannula through tissue to the pericardium under endoscopic visualization through the tip", and "laterally expanding a passage through tissue from the subxiphoid incision to provide a dilated cavity to facilitate insertion of the endoscopic cannula", and "said opening in the pericardium is provided by manipulating an entry instrument through the at least one access port of the rigid endoscopic cannula", and "gripping a flap of the pericardium under endoscopic visualization using an entry instrument introduced through the at least one access port of the endoscopic cannula".

These aspects of the claimed invention facilitate blunt dissection of tissue under visualization through an endoscope and the tip along a path from the subxiphoid incision toward the pericardium. The rigid endoscopic cannula promotes controlled and visualized passage through the diaphragm without fear of inadvertent puncture through the pericardium into the heart. The transparent tip at the distal end of the rigid endoscopic cannula greatly facilitates separating the muscle fibers of the diaphragm with diminished resistance relative to traditional

insertion of a large trocar that is necessary to accommodate a pericardioscope or other surgical instruments.

These aspects of the claimed invention are not disclosed in Oliva '156 which relies upon a flexible body analogous to a gastroendoscope (Col. 2, lines 47-50). This flexible instrument is not understood to include a transparent tip at a distal end that is capable of penetrating and dissecting tissue along a path from a subxiphoid entry incision to the pericardium in the manner as claimed by applicant. As Oliva '156 is currently understood, this reference discloses a difficult procedure that is prone to inadvertently injuring the heart. Specifically, Oliva '156 performs a subxiphoid incision and inserts a trocar through the muscle tissue of the diaphragm and the loose connective tissue along a path to the parietal pericardium. Trocars are commonly inserted without endoscopic visualization, and the diaphragm presents significant resistance to insertion of a trocar of sufficient size to accommodate a pericardioscope. There is therefore potential for puncturing the pericardium and injuring the heart in the absence of visual guidance as the trocar is inserted in accordance with the procedures disclosed in Oliva '156.

Nor is there any disclosure in this reference of any procedure for gripping and cutting a flap of the pericardium while spaced away from the underlying heart, in a manner as claimed by applicant. At best, this reference is understood to rely upon scissors for incising the pericardial sac (Col. 2, lines 50-52), with the

concomitant danger of puncturing the underlying heart. It is therefore respectfully submitted that Oliva '156 provides no disclosure or hint of suggestion of applicant's claimed method, and that claims 1-4, 6-7, and 25-27 as amended are now patentable to applicant.

Claims 34-37 have been rejected under 35 USC §102(e) as being anticipated by Roth '074. This rejection is respectfully traversed.

These claims, which have been amended merely to define the invention with greater particularity, specifically recite "laterally expanding the sheath responsive to passing the endoscopic cannula through the expandable sheath to form a working cavity in dilated tissue", and "laterally expanding the sheath responsive to withdrawing the endoscopic cannula from the sheath in a direction toward the proximal end thereof", and "dilating the working cavity to larger lateral dimensions than the endoscopic cannula responsive to insertion into the expandable sheath of surgical tools having dimensions greater than the cannula", and "advancing the surgical tool within the expandable sheath toward a distal end thereof to laterally expand the expandable sheath".

These aspects of the claimed invention facilitate sufficient dilation of tissue along the dissected cavity to accommodate a surgical instrument that is introduced therethrough toward the heart.

These aspects of the claimed invention are not disclosed in the cited reference. At best, the segment (col. 4, lines 12-20) of the specification cited by the Examiner merely describes a channel traversing the length of the shaft, and offers no hint or suggestion of expanding a laterally-expandable sheath in the manner as claimed by applicant. It is therefore respectfully submitted that claims 34-37 define the invention with sufficient particularity and distinctiveness to be patentable over the cited art.

Claims 11, 23, 24 have been rejected under 35 USC §103(a) as being unpatentable over Oliva '156 in view of Vaska et al. '605. This rejection is respectfully traversed.

These dependent claims are further limited from the predecessor claims by the specific recitations of "said surgical instrument advanced in step (d) is a device for performing epicardial mapping", and "said opening is formed at a location near the apex of the heart", and "the rigid endoscopic cannula is advanced during step (f) to a location at the anterior region of the heart and is then swept throughout regions including the posterior region of the heart".

These aspects of the claimed method invention promote controlled penetration of tissue with the aid of a rigid endoscopic cannula, along the path from the subxiphoid incision to the pericardium, and then through the pericardium

to selected regions of the heart, all under visualization through the endoscopic cannula.

These aspects of the claimed invention are not shown or suggested by the cited references considered either alone or in the combination proposed by the Examiner.

Specifically, Oliva '156 discloses use of a flexible body device that can be bent or otherwise shaped under control from the proximal end of the body, and such flexible body is not conducive to, or appropriate for, tissue dissection through diaphragm muscle for reasons as discussed in the above Remarks. And, Vaska et al. '605 B1 similarly relies upon flexible-body instruments inserted through a thoracic incision and through a pericardial penetration (Col. 3, lines 8-57). Thus, merely combining these references in the manner proposed by the Examiner is deficient of disclosure of the defined procedures, and fails to establish even a *prima facie* basis from which a proper determination of obviousness can be made. It is therefore respectfully submitted that the dependent claims 11, 23-24 as limited by the specific recitations of the predecessor claims and as further restricted by the recited limitations discussed above are now patentably distinguishable over the cited art.

Applicant points out that the claim limitations newly presented herein are supported by the original disclosure in manner sufficient for understanding by

persons of ordinary skill in the field, and in conformance with M.P.E.P. §§714.02; 2163.06, as follows:

Claim 1:

--inserting a rigid endoscopic cannula having a transparent tip at a distal end thereof;

advancing the tip of said endoscopic cannula through tissue to the pericardium under endoscopic visualization through the tip--

Support is set forth, for example, in Figures 7A-7D and at page 5, line 18 to 27.

Claim 2:

--comprising the steps for:--

Supported as acceptable claims language under 35 U.S.C. §112, ¶6.

Claim 6:

--laterally expanding a passage through tissue from the subxiphoid incision--

Supported, for example, by Figures 8A, 8B, 9B-9D and page 12, lines 27-30 and page 15, lines 9-21.

Claim 7:

--an entry instrument through the at least one access port of the rigid endoscopic cannula--

Supported, for example, by Figures 11A-11C and page 20, line 29 to page 21, line 16.

Claim 23:

--opening is formed at a location near the apex of the heart.--

Supported, for example, by Figure 10E and page 24 lines 12-24.

Claim 24:

--the rigid endoscopic cannula is advanced during step (f) to a location at the anterior region of the heart and is then swept throughout regions including the posterior region of the heart.--

Supported, for example, by Figures 11A-11C and page 25, lines 15-30.

Claim 25:

--an entry instrument introduced through the at least one access port of the endoscopic cannula--

Supported, for example, by Figures 8A, 8B, 10E and at page 24, lines 25-32.

Claim 26:

Limitation removed

Claim 27:

--cutting the flap of the pericardium while spaced away from the underlying heart.--

Supported, or example, by Figures 4, 5, 6A, 6B, 10E and page 24, lines 14-17.

Claim 34:

--a rigid endoscopic cannula having a laterally expandable sheath overlying the endoscopic cannula--

--inserting the rigid endoscopic cannula--

--advancing the endoscopic cannula through tissue toward the pericardium--

--laterally expanding the sheath responsive to passing the endoscopic cannula through the expandable sheath to form a working cavity in dilated tissue--

Supported, for example, by Figures 8A, 8B, 9A-9D, and page 23, lines 14 to page 24, line 11.

Claim 35:

--laterally expanding the sheath responsive to withdrawing the endoscopic cannula from the sheath in a direction toward the proximal end thereof.--

Supported, for example, by Figures 8A, 8B, 9B, 9C and page 22, lines 9-14.

Claim 36:

The method of claim 34 further comprising the step for:

--dilating the working cavity to larger lateral dimensions than the endoscopic cannula responsive to insertion into the expandable sheath--

Supported, for example, by Figures 8A, 8B, 9D and page 22, line 31 to page 23, line 1.

Claim 37:

--inserting into a proximate end of the expandable sheath a surgical tool for performing a cardiac procedure in which the surgical tool has a maximal lateral dimension greater than a maximal lateral dimension of the expandable sheath overlying the endoscopic cannula;

advancing the surgical tool within the expandable sheath toward a distal end thereof to laterally expand the expandable sheath--

Supported, for example, by Figures 8A, 8B, 9B, 9D and page 23, line 31 to page 24, line 11.

It is submitted that the above Remarks specifically point out adequate support in the original disclosure for each newly-presented claim limitation with sufficient particularity to conform to the provisions of M.P.E.P. §§714.02 and 2163.06.

Reconsideration and favorable action are solicited.

Respectfully submitted,
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ATTACHMENT: ABSTRACT OF THE DISCLOSURE